

Exhibit 37

PEEK TECHNICAL REVIEW

Wed. 5/25/94, 10:00am, Training Room B Santa Clara

AGENDA

- I. Introduction and Overview** *Bob Ainsworth - 15min.*
 - a) Project objective - target characteristics
 - b) Material options screened
 - c) General description of PEEK
 - d) Other medical device applications of PEEK
 - e) Biocompatibility of PEEK
 - f) Effect of radiation on PEEK
 - g) PEEK shaft tubing properties
 - * comparison to other polymer tubing
- II. PEEK OTW Catheter Performance** *Dan Cox - 15 min.*
 - a) Summary of performance of PEEK OTW catheters
 - * heart model and physician input
- III. PEEK Supply** *Steve Schaible - 10 min.*
 - a) Resin from ICI
 - * list of PEEK grades and ACS selection
 - * ICI supply to medical applications - status
 - b) Acutech
 - * ACS experience (tubing costs/consistency)
 - * agreement status
- IV. PEEK Extrusion (in-house)** *Steve Schaible - 20 min.*
 - a) process characteristics
 - b) process optimization plans
 - c) equipment needs for production process
 - d) cost estimate of tubing in production
- V. Post Processing** *Larry Wasicek - 10 min.*
 - a) expanding/necking
 - b) process description/consistency
 - c) equipment needs for production process
- VI. Joining** *Pat Urasake - 10 min.*
 - a) lap joint design
 - b) adhesives and process selection
 - c) testing results
- VII. Action Items** *Bob Ainsworth - 10 min.*
 - a) extrusion optimization/qualification plan
 - b) tubing source decision plan
 - c) supplier agreements
 - d) plans for necessary equipment acquisitions
 - e) effect of radiation sterilization study
 - f) other

PEEK TECHNICAL REVIEW

5 / 25 / 94

- 1. Overview**
- 2. PEEK OTW Catheter Performance**
- 3. PEEK Supply**
- 4. PEEK In-house Extrusion**
- 5. Post Extrusion Processing**
- 6. Joining / Bonding**
- 7. Action Items**

***Bob Ainsworth, Dan Cox, Steve Schaible, Larry Wasicek,
Pat Urasaki, Dave Young, Jeong Lee***

OVERVIEW

- 1. Project Objectives**
- 2. Initial Material Options**
- 3. PEEK Description**
- 4. PEEK Biocompatibility**
- 5. PEEK Radiation Resistance**
- 6. Comparative Mechanical Properties**

PROJECT OBJECTIVES

A PROXIMAL SHAFT MATERIAL WITH :

- 1. High Stiffness for Catheter Push**
- 2. High Strength for thin wall Low Profile Shafts**
- 3. Good Kink Resistance**
- 4. Low Cost (Readily Extrudable)**
- 5. Good Post Extrusion Processing Characteristics
(Acceptable Elongation and Bondability for
Catheter Assembly Processes)**

INITIAL MATERIAL OPTIONS

- 1. POLYIMIDE (Thermoset)**
- 2. POLYIMIDE WITH WIRE REINFORCEMENT (Steve Levin evaluation of braid and axial wire reinforced polyimide)**
- 3. POLYETHERETHERKETONE (VICTREX® PEEK)**
- 4. POLYETHERIMIDE (ULTEM® PEI)**
- 5. POLYETHERSULFONE (RADEL® PES)**
- 6. POLYARYLETHERKETONE (ULTRAPEK® PAEK)**
- 7. POLYPHENYLENE SULFIDE (PPS)**

PEEK (polyetheretherketone)

- High Temperature Thermoplastic
 - (m.p.: 633° F, process temp.: 700-750° F)
- Melt Stable (>1 hr at 752° F)
- Semicrystalline (max. crystallinity: 48%)
- Victrex® 381g grade from Victrex Corp.
- Biocompatible
- Radiation Resistant
- High Strength, Stiffness, Moderate Elongation and Kink Resistance

PEEK Biocompatibility

- **Other Medical Device Applications**
 - **Orthopedic Bone Plates (investigational)**
 - **Orthopedic Hip Implant (investigational)**
- **In-Vitro Biocompatibility (literature)**
 - **Negligible cellular response**
- **Muscle Implant Biocompatibility (literature)**
 - **Response similar to control PE**
- **ACS Cytotoxicity - *passed***
- **ACS Hemolysis - *passed***

PEEK RADIATION RESISTANCE

- After 1000 Mrads E-Beam, amorphous PEEK:
 - Modulus increased by 2.5%
 - Yield Strength decreased by 13%
 - Tensile Strength decreased by 20%
 - Elongation decreased by 22%
- PEEK was ranked more resistant than polyamide, less resistant than polyimide
- *from: POLYMER, Vol. 26, July 1985, pp. 1039-1045*

MECHANICAL PROPERTIES

<u>Material</u>	<u>Modulus</u>	<u>Elongation</u>	<u>Kink</u>
HDPE (X-Mndrl)	180 ksi.	150%	4
Hytrel 8238	72 ksi.	278%	5
PEBAX 7233	104 ksi.	285%	5
PET	291 ksi.	-----	2
PVDF (Kynar)	246 ksi.	125%	-----
Nylon 12	144 ksi.	206%	3
PEEK (SC)	422 ksi.	262%	3

MECHANICAL PROPERTIES

<u>Material</u>	<u>Modulus</u>	<u>Elongation</u>	<u>Kink Res.</u>
PEEK (Acutech)	415 ksi.	69%	3
PEEK (Air cooled)	422 ksi.	262%	3
PEEK (Wtr cooled)	370 ksi.	283%	3
PPS	279 ksi.	---	1
PES	323 ksi.	150%	3
PEI (Ultem)	346 ksi.	151%	3
PAEK (Ultrapek)	-----	-----	-----
Polyimide TS	470 ksi.	70%	2
Cobraid	679 ksi.	---	2

PEEK Performance Evaluations Completed

May 1993 - Heart Model vs Elastinite, PEEK was too small

1994 - Several heart models evaluating coaxial designs, transitions, PEEK inner member and elliptical distal shafts

March '94 - Heart model comparing elastinite and PEEK in both elliptical and coaxial versions

April '94 - Showed to Dr. Kent to compare PEEK and elastinite

April '94 - Heart model with Dr. Stone comparing PEEK and elastinite

May '94 - Perfused human heart with Dr. Hartzler - no results due to difficulties with model

No animal studies or human use to date

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PEEK Performance Results

Internal heart models

- PEEK performed very well
- Significantly better push than Edge
- Better push than Cobra because of less abrupt transition
- Guidewire movement equivalent to Edge and Cobra
- None of the PEEK devices had any kink problems
- Elastinite had slightly better guidewire movement

Dr. Kent

- Did not see major difference between PEEK and elastinite

Dr. Stone

- PEEK transition better than elastinite, less abrupt
- Likes very stiff proximal shafts - thought elastinite had slightly better longitudinal stiffness than PEEK
- Push of elastinite & PEEK is equivalent, both better than Cobra
- Guidewire movement torque in elastinite is slightly more one to one than in PEEK
- Track of both better than Edge, not quite as good as Cobra

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Elastinite vs PEEK Performance Differences

Transmits push from back end to distal tip

Elastinite is stiffer and feels somewhat more pushable
PEEK is much stiffer than PE and has very good push
The difference between PEEK and elastinite is small

Smooth guidewire movement

PEEK design uses graphite/HDPE inner member
Coating and straightness makes elastinite a little better
PEEK design is acceptable

Balloon catheter shaft doesn't kink during use

PEEK is more kink resistant than current Edge
Elastinite is more kink resistant than PEEK
Elastinite design can kink at transition and outer shaft
Overall kink resistance of designs is equivalent

Good visualization during proximal injections

Elastinite can be made .001"-.002" smaller than PEEK
PEEK design has adequate visualization

Can use smaller guiding catheters

PEEK performs better than Edge due to smaller size
Small difference between PEEK and elastinite

Customer Complaints

PEEK should virtually eliminate Edge shaft problems with RHV
Elastinite would not eliminate this problem

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OTW OPTIONS		Weighting	Edge	Edge w/ HC	Edge w/ HC, SLP	PEEK w/ HC, SLP	ACX V w/ HC, SLP	Cobra	Sleek	Future Competitor
Balloon And Catheter Performance			23	26	31	34	34	27	35	38
Slides through Tortous Artery Without Resistance	6.40	3	4	4.5	5	5	3	5	5.5	
Crosses Difficult Distal Lesions	6.39	3	3.5	4.5	4.5	4.5	3.5	5.5	5.5	
Transmits Push from Back end to Distal tip.	5.86	3	3	3	4	4.5	4	3	4.5	
Atraumatic Tip	5.80	3	3	4	4	4	3.5	5	5	
Crosses Second Lesion after Inflation	5.59	3	3.5	4.5	4.5	4.5	3.5	4.5	4.5	
Balloon Behavior During Inflation			20	20	22	22	22	17	21	22
Predictable Balloon Size during Inflation	5.84	3	3	3	3	3	2	3	3	
Predictable Balloon Rupture Pressure	5.64	3	3	3	3	3	2	3	3	
Ability to Dilate at Higher Pressures	5.20	3	3	4	4	4	3	5	5	
Balloon doesn't straighten the Artery	4.93	3	3	3.5	3.5	3.5	3	2.5	2.5	
Can Achieve Nominal Balloon Size at Low Pressure	4.70	3	3	3	3	3	3	2.5	3	
Guide Wire Concerns			23	23	23	23	24	23	21	23
Smooth Guide Wire Movement	6.15	3	3	3	3	3.5	3	1.5	3	
Simple Guide Wire Exchange	5.51	3	3	3	3	3	3	3	3	
Balloon Catheter doesn't cause G.W. to Kink in Anatomy	5.24	3	3	3	3	3	3	3	3	
Balloon Catheter doesn't cause G.W. to Kink during Exch.	5.00	3	3	3	3	3	3	3	3	
Easy-to-Load Guide Wire	4.49	3	3	3	3	3	3	3	3	
Compatible with .018 Guide Wires	3.95	3	3	3	3	3	3	3	3	
Operator Convenience Issues			15	15	15	15	15	15	16	16
Simple Balloon Catheter Exchange	5.45	3	3	3	3	3	3	3	3	
Balloon Catheter Shaft doesn't Kink during use.	5.41	3	3	3	3.5	3.5	3.5	3.5	3.5	
Good Inflation / Deflation Times	4.79	3	3	3	2.5	2.5	2.5	3	3	
Minimum Blood Loss at RHV	4.12	3	3	3	3	3	3	3	3	
Downsizing Systems			14	14	14	16	17	17	16	17
Good Visualization during Proximal Injections	5.41	3	3	3	3.5	4	4	3.5	4	
Can use Smaller Guiding Catheters	4.85	3	3	3	4	4	4	3.5	4	
Can use Two Balloon Catheters in a Guiding Catheter	4.50	3	3	3	3.5	3.5	3.5	3.5	3.5	
Can be used in Angiographic Catheters	3.49	3	3	3	3	3	3	3	3	
Cath Lab Staff Needs			5	5	5	5	4.6	5	5	5
Easy to Flush G.W. Lumen	3.69	3	3	3	3	3	3	3	3	
Stores well on Table	2.87	3	3	3	3	2.5	3	3	3	
Overall Ratings			100	103	110	115	117	104	114	121

PEEK TECHNICAL OVERVIEW

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PEEK SUPPLY

A) RESIN FROM VICTREX USA (previously ICI)

- * VARIOUS GRADES (see list)

- * ACS SELECTION CRITERIA

ACUTECH GRADE

- * VICTREX USA RESIN SUPPLY FOR MEDICAL APPLICATIONS

DENNIS HARRISON IS WORKING ON AGREEMENT

B) ACUTECH

- * TUBING COSTS

\$0.09 - \$0.11 / FT

- * CONSISTENCY

TOLERANCE +/- .0015"

- * AGREEMENT STATUS

CONFIDENTIALITY AGREEMENT IS SIGNED

VICTREX® PEEK

<u>GRADE</u>	<u>TYPE</u>	<u>NOTE</u>
150 P	Powder	Low viscosity for extrusion compounding
450 P	Powder	Standard viscosity for extrusion compounding
150 PF	Fine Powder	Low viscosity for blending & powder coating
450 PF	Fine Powder	Standard viscosity for compression molding, blending, and powder coating
150 G	Granules	Easy flow for injection molding of thin sections and complex parts
450 G	Granules	General purpose for injection molding and extrusion
150 GL 30	Glass Filled	Easy flow, 30% glass fiber reinforced for injection molding and extrusion
450 GL 30	Glass Filled	General purpose, 30% glass fiber reinforced for injection molding and extrusion
150 CA 30	Carbon Filled	Easy flow, 30% carbon fiber reinforced for injection molding
450 CA 30	Carbon Filled	Standard viscosity, 30% carbon fiber reinforced for injection molding
150 FC 30	Lubricated	Easy flow, 30% carbon/PTFE filler combination for injection molding
450 FC 30	Lubricated	Standard viscosity, 30% carbon/PTFE filler combination for injection molding
381 G	Depth Filtered	Grade for wire coating, film and monofilament

PEEK EXTRUSION (IN-HOUSE)

A) PROCESS CHARACTERISTICS

- * HIGH TEMPERATURE (750 - 800°F MELT)**
- * RELATIVELY HIGH PRESSURE (2800 PSI HEAD)**
- * HIGH DRYING TEMPERATURE (350°F)**

B) PROCESS OPTIMIZATION

* DOE	<u>factors</u>	<u>responses</u>
	melt temp	tensile modulus
	addr	ultimate strain
	air gap	crystallinity
		kink resistance
		dimensional stability

C) EQUIPMENT NEEDS FOR PRODUCTION PROCESS

- * HEAD INSULATION JACKETS**
- * HIGHER TEMPERATURE DRYING OVENS**

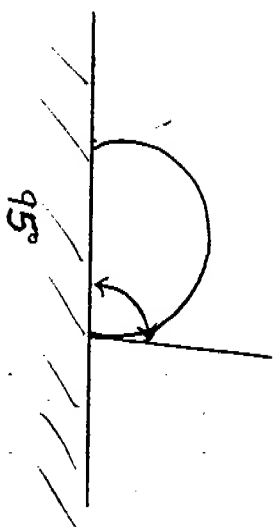
D) COST ESTIMATE OF TUBING IN PRODUCTION

<u>SITUATION</u>	<u>BREAKDOWN</u>	<u>COST/FT</u>
CURRENT (PE)	MATERIAL	\$0.005 - 0.01
	RESOURCES	\$0.18 - 0.185
	TOTAL	\$0.19
NEXT .014 (PEEK)	MATERIAL	\$0.25 - 0.55
	RESOURCES	\$0.18 - 0.185
	TOTAL	\$0.43 - 0.74

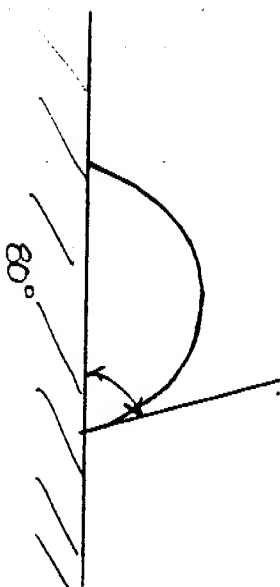
- * RESOURCES (equipment depreciation, tooling, engineering)**
- * RESIN COST (PE = \$1/LB, PEEK = \$55/LB)**

CONTACT ANGLE
(with water)

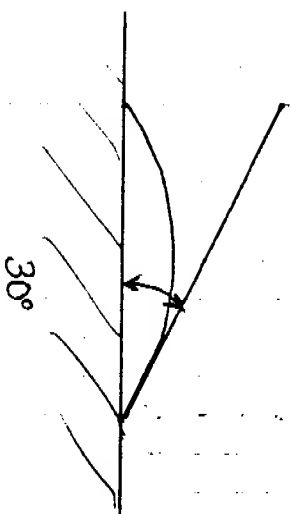
UNTREATED PEG600



UNTREATED PEEK



ARGON PLASMA PEG600



ARGON PLASMA PEEK

